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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/905,508	08/04/1997	LALEH SHAYESTEH	023070-06772	5513

7590

02/25/2004

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TWO EMBARCADERO CENTER 8TH FLOOR
SAN FRANCISCO, CA 941113834

EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT PAPER NUMBER

1634

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/905,508

Applicant(s)

SHAYESTEH ET AL.

Examiner

Jehanne Souaya Sitton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 39 is/are allowed.
- 6) ☒ Claim(s) 37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Currently, claims 37-39 are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are newly applied. They constitute the complete set being presently applied to the instant Application. This action is NON-FINAL.

Inventorship

2. In view of the papers filed 10/14/2003 and 2/3/2003, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(c). The inventorship of this application has been changed by addition of inventor Yiling Lu.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of the file jacket and PTO PALM data to reflect the inventorship as corrected.

Withdrawn Rejections

3. The amendment in claim 37 to PI3 kinase inhibitors (from PI kinase inhibitors) and Applicant's arguments, see page 6, lines 8-16, filed 12/12/2003, with respect to there being a wide variety of PI3 kinase inhibitors with different structural features have been fully considered and are persuasive. This class (PI 3 kinase inhibitors) represents structurally different compounds

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and includes compounds that were known prior to the filing date of applicants' invention. The 112/first paragraph rejection based on a lack of written description of claims 37 and 38 has been withdrawn.

4. The amendment to claim 37 to recite PI3 kinase inhibitors and 3q26.3 as well as applicants arguments with regard to the claims being drawn to inhibitors that inhibit PI3 kinase enzyme activity and that the specification excludes nucleic acids and gene therapy as inhibitors of PI3 kinase enzyme activity (se para bridging pages 5 and 6 of the response) have been thoroughly reviewed and were found persuasive to overcome the rejection under 35 USC 112/first paragraph for lack of enablement, made in section 5 of the previous office.

5. The amendment to claim 37, to recite 3q26.3 has obviated the rejection of claims 37-39 made in section 8 of the previous office action with regard to New Matter.

6. The amendment to claim 37 to include the recitation of "cancer" in line 3 has obviated the rejection of claims 37-39 made in sections 9 and 10 of the previous office action under 112/2nd paragraph.

7. Applicant's arguments with respect to claims 37 and 38, rejected under 35 USC 102(b) as being anticipated by Bonjouklian, in section 12 of the previous office action have been considered but are moot in view of the new ground(s) of rejection.

8. The submission of a declaration signed by the appropriate inventive entity in the responses filed 2/3/2003 and 10/14/2004 has overcome the rejection of claims 37-39 under 35 USC 102(f) made in section 13 of the previous office action. The rejection is accordingly withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonjouklian et al (hereinafter referred to as Bonjouklian; US Patent 5,378,725; 1/3/1995), in view of Arnold et al (hereinafter referred to as Arnold; Genes, Chromosomes, and Cancer, vol. 16, pages 46-54, 1996) and Volinia et al (hereinafter referred to as Volinia; Genomics, vol. 24, pp 472-477; 1994) and further in view of (in the alternative) Xiao et al (hereinafter referred to as Xiao, International Journal of Oncology; vol. 6, pp 405-411, 1995) or Skorski et al (hereinafter referred to as Skorski, Blood, vol. 86, pp 726-736, 1995).

Bonjouklian et al teach and claim a method of treating PI3 kinase dependent neoplasms in mammals by administering non peptidic inhibitors (see col. 3, col. 4, table 1; col. 6, lines 49-60; and claims 1-9). Bonjouklian et al specifically teach a method for treating a phosphatidylinositol 3 kinase dependent condition in a mammal, such as abnormal cell growth as found in neoplasms, such as ovarian cancer, by administering a phosphatidylinositol 3 kinase inhibiting amount of a compound as shown in cols 2, 3, and 4 (col. 6, lines 49-col. 7, line 2). Bonjouklian et al teach how to determine quantity of compound, such as wortmannin (an inhibitor of PI3 kinase phosphoinositide phosphorylation), to produce a desired therapeutic effect (col. 7, especially lines 54-62). It is noted that Bonjouklian et al do not specifically teach

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treating a patient with a “population of ovarian cancer cells comprising cells in which 3q26.3 is amplified”, however he does teach treating a “PI3 kinase dependent neoplasm” and it was known in the art at the time the invention was made that the region of chromosome 3q26 was commonly amplified in ovarian tumors as taught by Arnold (see page 49, col 2, 3q26 is increased in 42% of cases). Further, Volinia teaches that the catalytic p110 alpha subunit of PI 3 kinase (PIK3CA) is found in 3q26.3. Additionally, Xiao and Skorski teach that wortmannin, a known PI3 kinase inhibitor and taught by Bonjouklian as a treatment for ovarian cancer, was able to suppress growth of gastric cancer cells (see abstract of Xiao) and selectively inhibited the proliferation of leukemic cells (see pages 729 –730 and abstract of Skorski). Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use the PI3 kinase inhibitor wortmannin to treat ovarian cancer as taught by Bonjouklian, and to include treatment of any ovarian cancer, including ovarian cancer cells which had regions of chromosome 3q26, including 3q26.3, amplified as Arnold taught that such region was amplified in ovarian tumors. Further, Volinia teaches that PIK3CA was found in 3q26.3. Therefore, from the combined teachings of Volinia and Arnold, the ordinary artisan would be taught that ovarian cancer tumors would include those that had region 3q26 amplified, and that PIK3CA was found in the same region, particularly 3q26.3 and would have therefore realized that the method of Bonjouklian, that is treatment of PI3 kinase dependent ovarian cancer, would include ovarian tumors which were characterized by the probable amplification of a chromosomal region containing a PI3 kinase. The ordinary artisan would have had a reasonable expectation of success that wortmannin, as taught by Bonjouklian, would be an effective inhibitor of

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pathological proliferation of *any* ovarian tumor cell because it was known in the art that wortmannin inhibited growth of different cancerous cells as taught by Xiao and also Skorski.

Conclusion

11. Claims 37 and 38 are not allowable over the cited prior art. Claim 39 is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0572. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

Note: The examiner's name has changed from Jehanne Souaya to Jehanne Sitton. All future correspondence to the examiner should reflect the change in name.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (703) 872-9306.

Jehanne Sitton

Jehanne (Souaya) Sitton

Primary Examiner

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2/19/04